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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE FEB 26 2002

Commissioner for Patents  
Washington, D.C. 20231

TECH CENTER 1600/2900

In re PATENT APPLICATION ofInventors: **Allen et al.**Appln. No.: **09/815,944**Filed: **March 22, 2001**Title: **Transgenic Mice Containing Melanocyte Stimulating  
Hormone Receptor Gene Disruptions**Group Art Unit: **1633**Examiner: **Qian, Celine X.**Docket/Order #: **R-654**Deposit Acct **50-1271**Customer # **26619**Date: **January 31, 2002**

## RESPONSE TO RESTRICTION REQUIREMENT TRANSMITTAL

Sir:

Please file the enclosed response in the above-identified application. The signature below is to be treated as the signature to the enclosure in absence of a signature thereto.

## FEE REQUIREMENTS FOR CLAIMS AS AMENDED

| 1. Small Entity previously claimed   | Claims remaining | Highest # paid for | Present Extra | Small Entity | Add'l Fee | Fee Code          |
|--|------------------|--------------------|---------------|--------------|-----------|-------------------|
| 2. Total Claims  | 16               | minus 33 = 0       | x             | \$9. =       | + 0       | 203               |
| 3. Independent Claims  | 7                | minus 14 = 0       | x             | 42. =        | + 0       | 202               |
| 4. If amendment enters multiple dependent claim(s) for the first..... add  |                  |                    |               | \$140. =     | +         | 204               |
| 5. Original due date: <b>January 31, 2002</b>  |                  |                    |               |              |           |                   |
| 6. <b>Petition is hereby made</b> to extend the due date to cover the date this response is filed, for which the requisite fee is enclosed |                  |                    |               |              |           | 215<br>216<br>217 |
| 7. Enter any previous extension fee paid and (subtract)-   |                  |                    |               |              |           |                   |
| 8. Total fee for extension of time: <b>+\$0</b>  |                  |                    |               |              |           |                   |
| 9. If Terminal Disclaimer is enclosed, add Rule 20(d) official fee.....  |                  |                    |               |              |           | 248               |
| 10. If IDS enclosed requires Official Fee, ..... add   |                  |                    |               |              |           | 126               |
| or if Rule 97(d) Petition, ..... add   |                  |                    |               |              |           | 122               |
| 11. After-Final Request Fee per Rules 129(a) and 17(r).....  |                  |                    |               |              |           | 246               |
| 12. No. of additional inventions for examination per Rule 129(b):..... ea x  |                  |                    |               |              |           | 249               |
| 13. Petition fee for   |                  |                    |               |              |           |                   |
| <b>TOTAL FEE: <input checked="" type="checkbox"/> CHARGE AUTHORIZATION <input type="checkbox"/> ENCLOSED = \$0</b>                         |                  |                    |               |              |           |                   |

Charge Statement: The Commissioner is hereby authorized to charge any missing or insufficient fees relative to this application, or credit any overpayment, to our Account/Order Nos. above, for which purpose a duplicate copy of this sheet is enclosed.

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## CERTIFICATE OF MAILING

I certify that this paper and listed enclosures are being deposited with the U.S. Postal Service as First Class mail, post paid, in an envelope addressed to the Commissioner for Patents, BOX AMENDMENT, Washington, D.C. 20231 on January 31, 2002.

*Deborah A. Mojarro*  
Deborah A. Mojarro

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

FEB 26 2002

TECH CENTER 1600/2900

Application of: ALLEN *et al.*

FEB 19 2002

Group Art Unit: 1633

Serial No.: 09/815,944

Examiner: Qian, Celine X.

Filed: March 22, 2001

Attorney Docket No.: R-654

For: TRANSGENIC MICE CONTAINING MELANOCYTE STIMULATING HORMONE  
RECEPTOR GENE DISRUPTIONS

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Office Action mailed December 31, 2001, concerning the Examiner's restriction to the claims, Applicants hereby provisionally elect, with traverse, Invention I (claims 1-10 and 17-21), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a melanocyte stimulating hormone receptor gene, a melanocyte stimulating hormone receptor gene knockout non-human animal and a method of making said non-human animal.

In the restriction, the Examiner asserts that claims 1-25 are drawn to six distinct subjects, grouped as: Invention I (claims 1-10 and 17-21), drawn to a targeting construct, a method of making said targeting construct, a cell comprising a disruption in a melanocyte stimulating hormone receptor gene, a melanocyte stimulating hormone receptor gene knockout non-human animal and a method of making said non-human animal; Invention II (claims 11, 13 and 23), drawn to a method of identifying an agent that modulates melanocyte stimulating hormone receptor gene expression; Invention III (claims 12 and 14), drawn to a method of identifying an agent that modulates melanocyte stimulating hormone receptor gene function; Invention IV (claims 16 and 25), drawn to an agent that modulates melanocyte stimulating hormone receptor gene expression or function; Invention V (claims 22 and 24), drawn to a method of identifying an agent that ameliorates or modulates hypoactive behavior; and Invention VI (claim 25), drawn to

an agent that ameliorates or modulates hypoactive behavior, with claim 15 generic to groups II and III, and claim 25 generic to groups IV and VI. Applicants respectfully request reconsideration and withdrawal of the requirement.

Specifically, the Examiner asserts that the claims of Invention I are materially different from the claims of Invention II and are thus patentably distinct inventions. The Applicants disagree with the Examiner's conclusion in that the claims of Invention I are related to the methods recited in the claims of Invention II and would not require a separate search or examination that would seriously burden the Examiner.

The Examiner further asserts that the claims of Invention I and Invention III are patentably distinct because the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods of identifying agents that modulate function of a melanocyte stimulating hormone receptor recited in the claims of Invention III and the claims of Invention I are related and would not require a separate search or examination that would seriously burden the Examiner.

The Examiner also asserts that the claims of Invention I are patentably distinct as the inventions are drawn to materially different compositions and methods that are not directly related to the claims of Invention IV. The Applicants disagree with the Examiner's conclusion in that the agents that modulate melanocyte stimulating hormone receptor gene expression or function recited in the claims of Invention IV and the claims of Invention I are related and thus, would not require a separate search or examination that would seriously burden the Examiner.

It also asserted by the Examiner that the claims of Invention I and Invention V are patentably distinct as the inventions are drawn to materially different compositions and methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods of identifying agents that ameliorate or modulate hypoactive behavior recited in the claims of Invention V are related to the claims of Invention I. A search and examination of these claims can be made without serious burden on the Examiner.

According to the Examiner, claims of Invention I and the claims of Invention VI are patentably distinct because the inventions are drawn to materially different compositions and methods that are not directly related. The Applicants disagree with the Examiner's conclusion in

that the agents recited in the claims of Invention VI are related to the claims of Invention I and that a search and examination of these claims can be made without serious burden on the Examiner.

The Examiner further asserts that the claims of Invention II and Invention III are patentably distinct as the inventions are drawn to methods that require different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention II and the methods recited in the claims of Invention III both require the same starting materials and that a search and examination of the claims of Inventions II and III can be made without serious burden on the Examiner.

The Examiner further contends that the claims of Invention II are patentably distinct from the claims of Invention IV as the agent recited in the claims of Invention IV can be identified by other methods. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV are related to the methods of Invention II. Thus, a search and examination of these claims can be made without serious burden to the Examiner.

The Examiner also asserts that Inventions II and V are patentably distinct because the inventions are drawn to different starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods of Invention II require the same or related starting materials as the methods of Invention V. Further, the method comprising the step of determining whether the agent modulates melanocyte stimulating hormone receptor gene expression in the transgenic mouse, wherein the agent has an effect on hypoactive behavior recited in the claims of Invention II requires the same mode of operation as the methods of identifying agents that ameliorate/modulate hypoactive behavior recited in the claims of Invention V. Therefore, a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner further concludes that the claims of Invention II are patentably distinct from the claims of Invention VI because the inventions are drawn to methods and compositions that are not directly related. The Applicants disagree with this conclusion in that the method of identifying an agent comprising the step of determining whether the agent modulates melanocyte stimulating hormone receptor gene expression in the transgenic mouse, wherein the agent has an effect on hypoactive behavior can produce an agent of Invention VI. Further, Applicants assert

that a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner also asserts that the claims of Invention III are patentably distinct from the claims of Invention IV as to the process of making and the product made. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV are related to the methods recited in the claims of Invention III and thus, a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner further asserts that Inventions III and V are patentably distinct because the inventions are drawn to methods that require starting materials and modes of operation. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention III and the methods recited in the claims of Invention V both require the same starting materials and that a search and examination of the claims of Inventions III and V can be made without serious burden on the Examiner.

The Examiner also asserts that the claims of Invention III are patentably distinct from the claims of Invention VI because the inventions are drawn to methods and compositions that are not directly related. The Applicants disagree with the Examiner's assertion in that the methods recited in the claims of Invention III are related to the agents recited in the claims of Invention VI and that a search and examination of these claims can be made without serious burden to the Examiner.

As asserted by the Examiner, the claims of Invention IV are patentably distinct from the claims of Invention V because the inventions are drawn to compositions and methods that are not directly related. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention IV are related to the methods recited in the claims of Invention V and thus, a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner further asserts that Inventions IV and VI are patentably distinct as the inventions are drawn to materially distinct compositions. Applicants disagree with the Examiner's assertion in that the claims of Inventions IV and VI are related and a search and examination on these claims can be made without serious burden to the Examiner.

The Examiner also concludes that the claims of Invention V are patentably distinct from the claims of Invention VI. The Applicants disagree with the Examiner's conclusion in that the agents recited in the claims of Invention VI and the methods recited in the claims of Invention V are related and a search and examination on these claims can be made without serious burden to the Examiner.

Although Applicants have provisionally elected Group I for purposes of advancing prosecution of the present application, Applicants contend, for the foregoing reasons, that the restriction requirement is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of the requirement.

Respectfully submitted,

Date: 1/31/02

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Enclosures